Remarks

By the present amendment claims 52-56 have been added. Claims 25, 27, 29, 31-32, 35, 40-41, 43 and 47-56 are pending.

Support for the recitation of the term recombinant polypeptide in the claims can be found in, for example, ¶¶ 1, 10, 34, 37, 40, 167-169. No new matter is added.

Claim Rejections - 35 U.S.C. §112, First Paragraph

Claims 25, 27, 29, 31, 32, 35, 40, 41, 43 and 47-51 stand rejected under 35 U.S.C. §112, first paragraph based on an assertion that the specification, while being enabling for a polypeptide consisting of the sequence of the amino acid SEQ ID NO: 2, a fusion protein comprising the amino acid sequence SEQ ID NO:2, and an immunogenic composition comprising the amino acid sequence SEQ ID NO:2 does not reasonably provide enablement for an isolated polypeptide that comprises a fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, fusion protein or immunogenic composition comprising said fragments.

Applicant respectfully puts forth that each of the currently pending claims are fully enabled and described by the specification. The specification of the instant application provides a full disclosure of the amino acid sequence of SEQ ID NO: 2 and the nucleotide sequence SEQ ID NO: 1, which encodes the polypeptide of SEQ ID NO: 2. The specification also provide substantial guidance for producing polypeptide fragments and further disclosed recombinant techniques for producing polypeptides (see pages 45-47). It should also be noted that it was well within the abilities and skill of one of ordinary skill in the art to produce polypeptides of various sizes using recombinant techniques, especially when provided with both the polypeptide and nucleotide sequences of a given protein. Thus, the invention as claimed is fully enabled. The Examiner's concerns regarding "unlimited and unknown amino acids of SEQ ID NO: 2" are misplaced. The claims of the instant application clearly define the metes and bounds of the instant invention, that is the amino acid sequence SEQ ID NO:2; and immunogenic fragments of at least 15 contiguous amino acids of SEQ ID NO:2 wherein the immunogenic fragment induces an antibody or T-cell mediated immune response that recognizes the polypeptide SEQ ID NO:2. Thus, the claims do not encompass "unlimited and unknown amino acids of SEQ ID NO: 2". At minimum, the specification teaches the polypeptide of SEQ ID NO: 2 and fragments thereof that induce an immune response. That these fragment may or may not be distinguishable from each

other, as seems to be a concern of the Examiner, is not of importance as each of these fragments are encompassed by the instant invention, as one of ordinary skill in the art would immediately recognize. As such, Applicant puts for that the currently pending claims are properly enabled and described by the instant specification.

With regard to the unpredictability of protein chemistry, Applicants note that the art has recognized the difficulties associated with processing of protein fragments, and has devised methods for overcoming inefficient processing of protein fragments in studies of human T-cell responsiveness. These methods were available at the time of the filing of the instant application and were within the purview of those of skill in the art. For instance, in Reece et al., *J. of Immunol.* **1993**, 6175-6184 (which was attached as Exhibit A in Applicant's amendment of 4/19/04) the difficulties associated with inefficient protein processing in connection with studies of T-cell responsiveness were recognized (p. 6175, ¶ 1). In Reece et al., the difficulties of protein processing were overcome by synthesizing overlapping dodecapeptides on pins to map T-cell epitopes of tetanus toxin. Pools of 20 peptides each were used to simplify the mapping assays. Thus, it was practical to synthesize a large number of peptides, and the initial screen needed only to assay sixty to seventy pools. Pools that generated strong responses were deconvoluted by assaying the members of the pool. That such experimentation using a multipin method to screen for antigens is ordinary in this art is illustrated in *Current Protocols in Immunology* **1997** 9.7.1-9.7.19 (which was attached as Exhibit B to the amendment of 4/19/04) and Reece et al., 172 *J. of Immunol.* **1994** 241 (previously attached as Exhibit C). The Examiner's concerns regarding "unlimited and unknown amino acids of SEQ ID NO: 2" are misplaced. The claims of the instant application clearly define the metes and bounds of the instant invention, that is the amino acid sequence SEQ ID NO:2; and immunogenic fragments of at least 15 contiguous amino acids of SEQ ID NO:2 wherein the immunogenic fragment induces an antibody or T-cell mediated immune response that recognizes the polypeptide SEQ ID NO:2. Thus, the claims do not encompass "unlimited and unknown amino acids of SEQ ID NO: 2". Consequently, given the teachings of the specification that includes the structural formula of SEQ ID NO:2 and experimental methods well-known in the art at the time of filing, Applicants assert that the claimed polypeptides are enabled.

In light of the above discussion, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

Conclusion

Applicant believes this response to be a full and complete response to all outstanding rejections in this application. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 61-67 and 69-73. As the application is believed to be in condition for allowance, Applicants respectfully request a Notice of Allowability. The Examiner is invited to contact the undersigned representative should any further issues arise

Respectfully submitted,

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